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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No
08/973,381

Applicant(s)

Hebert

Examiner

Ardin Marschel

Art Unit

1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 2, 2001
- 2a) This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) All b) ☐ Some* c) ☐ None of:
- 1 Certified copies of the priority documents have been received.
- 2 Certified copies of the priority documents have been received in Application No. _____
- 3 Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☒ Interview Summary (PTO-413) ~~PTO-413~~ (4 copies)
- 19) Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other Attachment to PTO-948

Applicants' arguments, filed 1/21/01 and discussed in the interviews of 1/31/01, 5/24/01, 6/4/01, and 6/29/01; have been fully considered and they are deemed to be persuasive to overcome the previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

Due to the overcoming of the rejections against the elected specie compound VI (See, for example, specie VI in claim 1.), the examination is hereby extended to cover the remaining species of compounds.

Due to the newly applied rejections hereinbelow summarized the finality of the office action, mailed 8/1/00, is hereby withdrawn. The Notice of Appeal, filed 2/2/01 is also deemed moot considering this reopening of prosecution.

Applicant is hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". It is noted that the present drawings in the instant application are apparently informal as containing extraneous markings as well as leftover marking from PCT processing. Due to the above notification Applicant is required to submit drawing corrections within the time period set for

responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Claims 1-26 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the making of compounds I-VI, does not reasonably provide enablement for the making of compounds VII-XI. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are

considered, a sufficient amount for a prima facie case are discussed below.

Consideration of the instant specification reveals that the making of compounds VII - XI requires the essential subject matter in several printed publications which are incorporated by reference. This is improper and lacks enablement in the instant disclosure as summarized in the below paragraph. For compound VII, apparently the publication cited on page 101, lines 4-5, contains essential subject matter for the preparation of one of the species therein. Also, for compound VII, apparently the publication cited on page 102, lines 27-28, contains essential subject matter for the preparation of one of the species therein. For the synthesis of compounds X and XI, Example 138 on page 129 requires methyl 2-diazoacetoacetate which has not been found in common chemical catalogs and thus lacks enablement for the synthesis to support compounds X and XI. For compound IX, apparently the publication cited on page 131, lines 27-29, contains essential subject matter for its preparation. Lastly, no synthetic procedures have been found for compound VIII. These compounds contain reactive nitrogens, oxygens, etc. and as such are synthesized with complex series of steps to direct the synthesis to the desired end product. It is deemed undue experimentation to prepare such complex compounds with complex syntheses without specific synthetic guidance which is lacking in

the instant disclosure for compounds VII - XI thus supporting this rejection.

The incorporation of essential material by reference to a foreign application or foreign patent or to a publication inserted in the specification is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or applicant's attorney or agent, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. *In re Hawkins*, 486 F.2d 569, 179 USPQ 157; *In re Hawkins*, 486 F.2d 579, 179 USPQ 163; *In re Hawkins*, 486 F.2d 577, 179 USPQ 167.

No claim is allowed.


Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1993), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

July 30, 2001


ARDIN H. MARSCHEL
PRIMARY EXAMINER